510(k) Summary

MAR 1 3 2013

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 10, 2012

Submitter: GE Healthcare, (GE Medical Systems, LLC)
3200 N. Grandview Blvd.
Waukesha, WI 53188

Primary Contact Person: Michelle Huettner
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Device: Trade Name: Optima MR450w

Common/Usual Name: Magnetic Resonance Diagnostic Device

Classification Names: 892.1000

Product Code: LNH

Predicate Device(s): Optima MR450w (K113490)

Device Description: The 1.5 GE Optima MR450w features a superconducting magnet operating at 1.5 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms. The Silenz Imaging Application using the 3D Radial Pulse sequence reduces the acoustic noise that is generated during an MR examination. This application is compatible on the Optima MR450w system with GEM

configuration. The 1.5T GE Optima MR450w is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Intended Use: The Optima™ MR450w is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the Optima™ MR450w reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Technology: The modified Optima MR450w employs the same fundamental scientific technology as its predicate device, the Optima MR450w. It is still a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The images produced with the Optima MR450w reflect the spatial distribution or molecular environment of the nuclei which exhibit magnetic resonance. The addition of the Silenz feature does not alter the overall technology of the Optima MR450w System.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Optima MR450w scanner with the GEM configuration and addition of the Silenz Imaging Application complies with the following voluntary standards:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-1-6
- IEC 60601-2-33

- IEC 62304
- ISO 14971

In addition, this MR scanner is in compliance with the applicable NEMA standards, including NEMA PS3.1-3.18 for DICOM conformance.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The non-clinical tests have been summarized in the Verification testing that was completed for the Optima MR450w System with the Silenz application. The testing was completed with passing results per the pass/fail criteria defined in the test cases. This supports substantial equivalence to its predicate (Optima MR450w) because it was also developed under quality assurance Design Controls. In addition, it is in compliance to the same Standards.

Summary of Clinical Tests:

The subject of this premarket submission, Optima MR450w, did not require external clinical studies to support substantial equivalence. Internal scans were conducted as part of validation for workflow and image quality for the addition of the Silenz Imaging Application. Sample clinical images are included in this submission.

Conclusion: GE Healthcare considers the Optima MR450w to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Michelle Huettner
Regulatory Affairs Leader
GE Healthcare (GE Medical Systems, LLC)
3200 N. Grandview Blvd
WAUKESHA, WI 53188

Re: K123522
Trade/Device Name: Optima MR450w
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, MOS
Dated: February 11, 2013
Received: February 12, 2013

Dear Michelle Huettner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123522

Device Name: Optima MR450w

Indications for Use: The Optima™ MR450w is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the Optima™ MR450w reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123522